AUG 3 0 2000

510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- COMMON/USUAL NAMES: Balloon Dilatation Catheter
- TRADE/PROPRIETARY NAME: Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Biliary Catheter	78 FGE	876.5010

- DEVICE PANEL/BRANCH: GASTROENTEROLOGY-UROLOGY (GU) GASTRO-RENAL (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760, Owner/Operator No. 9912058
- CONTACT PERSON: Abby Lipman, Senior Regulatory Affairs Specialist

DESCRIPTION OF DEVICE

The Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter is a Rapid Exchange™ double lumen catheter with a balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow duct segments, as well as the Sphincter of Oddi.

INDICATIONS FOR USE

The Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter is recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi.

The Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter is substantially equivalent to the currently-marketed Maxforce Biliary Balloon Dilatation Catheter and TandemRX. The major components of the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter are the catheter shaft , balloon and the Rapid Exchange feature. A thorough comparison of the descriptive characteristics between the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter to verify its safety and performance. A biocompatibility assessment was performed on the patient and fluid-contact materials of the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter is substantially equivalent to the currently-marketed Maxforce Biliary Balloon Dilatation Catheter and TandemRX. A comparison of the descriptive characteristics of these products demonstrate the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Ms. Abby Lipman
Senior Regulatory Affairs Specialist
Boston Scientific Corp.
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K001338
Microvasive Rapid Exchange™ Biliary Balloon Dilatation Catheter
Dated: August 4, 2000
Received: August 7, 2000
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

Dear Ms. Lipman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE

510(k) Number: K001338

Device Name: Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter

Indication for Use:

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The Microvasive® Rapid Exchange™ Biliary Balloon Dilatation Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001338